K072224

SEP 2 1 2007

Global FabTech Wheelchair (Shanghai) Co., Ltd.

No. 318, TianFu Rd., Jiuting Songjiang, Shanghai, 201615, China
TEL: +86-21- 6763-2308 FAX: +86-21- 6763-2309

510(k) Summary

Device

Trade name: **Zip'r PC powered wheelchair**

Common name: **Powered wheelchair**

Classification name: **Powered wheelchair**

Medical specialty (Panel): **Physical Medicine Device**

Regulation number: **890.3860**

Product Code: **ITI**

Classification: **Class II**

Predicate devices

CWD01 (K062888) / EMG Technology Co. Ltd.

Intend use of device

Zip'r PC powered wheelchair is intended for an indoor/outdoor power wheelchair that provides transportation for disabled or elderly persons limited to a seated position.

Device description:

The **Zip'r PC** powered wheelchair is an indoor/outdoor powered wheelchair that is battery operated. The design of this wheelchair is basically similar to other powered wheelchairs that are already on the market. By providing a powered wheelchair that breaks down into two manageable components (seat frame, body frame with motors and battery pack), a user can have a more practical alternative when traveling long distances by bus, train, etc.

Substantial equivalence:

The **Zip'r PC powered wheelchair** is substantially equivalent to the **CWD01 (K062888)** manufactured by **EMG Technology Co. Ltd..**

There are minor differences in performance specifications of the powered wheelchairs, these differences do not alter the intended function and use of the device, nor do they raise any new questions pertaining to safety or effectiveness. Therefore, **Global FabTech Wheelchair (Shanghai) Co., Ltd.** believes that the **Zip'r PC** powered wheelchair is substantially equivalent to legally marketed devices currently in commercial distribution.

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The substantial equivalence comparison of the **Zip'r PC** and CWD01

	Zip'r PC	CWD01 (K062888)
Intended use	It is motor driven, indoor and outdoor transportation vehicles with the intended use to provide mobility to disabled or elderly persons limited to a seated position.	It is intended for medical purposes to provide mobility to persons restricted to a sitting position.
Maximum loading	136 kg (300 lbs)	136 kg (300 lbs)
Overall height	990 mm (39")	1130 mm (44.5")
Overall length	1020 mm (40")	900 mm (35.4")
Overall width	630 mm (24")	650 mm (25.6")
Seat overall height	570 mm (23")	
Seat overall width	609mm (24")	18"
Seat overall depth	520mm (21")	
Seat overall weight	16 kg (35 lbs)	
Motor output	DC 24V, 320 W, 2 Pcs	260W x DC24V × 2Pcs
Controller	PG VRI	Dynamic Shark
Rear wheel drive	Sealed transaxle direct drive	
Battery	Lead-Acid 12V × 33AH × 2PCs	Lead-Acid 12V×35AH×2PCs
Charger	DC 24V 5 AMP (Automatic Type) off-board	DC 24V 5A, off-board
Front wheel	10" Solid tire × 2 PCs	6" penumatic tire × 2 PCs
Rear wheel	8" Solid tire × 2 PCs	10" PU foaming tire × 2 PCs

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(Continuous) The substantial equivalence comparison of the **Zip'r PC** and CWD01

	Zip'r PC	CWD01 (K062888)
Armrest	Fixed	Removable
Break system	Intelligent regenerative electromagnetic brake	
Braking distance	Forward: 1.4 m(56") at max speed	
Net weight w battery	68 kg (150 lbs)	83.5kg (183.7 lbs)
Slope grade ability	8 degree	12 degree
Per-charge distance	Up to 40 km (25 miles)	40 km (24 miles)
Maximum speed	Up to 6.4 km/hr (4 mph), variable	5 km/h (3.2 mph)
Turning radius	0.51 m (20")	
Maximum curb height	25 mm (1")	
Suspension	Front: No, Rear: No	Cross brace
Horn	Yes	
Anti-tip wheels	Yes	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 21 2007

Global FabTech Wheelchair (Shanghai) Co., Ltd.
% Mr. Edward Dong
No. 318, TianFu Rd.
Jiuting Songjiang
Shanghai, 201615, China

Re: K072224
Trade/Device Name: Zip'r PC
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered Wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: August 7, 2007
Received: August 10, 2007

Dear Mr. Dong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3. Device descriptive information

3.1 Statement of indication for use

Statement of Indications for Use

510(k) Number (if known): _____

Device Name: **Zip'r PC**

Indications for Use:

The **Zip'r PC** powered wheelchair is motor driven, indoor and outdoor transportation vehicles with the intended use to provide mobility to disabled or elderly persons limited to a seated position.

Prescription Use _____ Over-The-Counter Use __X__

(Part 21 CFR 801 Subpart D) AND/OR (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE) Page 1 of 1

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K072224

(Posted November 13, 2003)